

Food and Drug Administration Minneapolis District 240 Hennepin Avenue Minneapolis MN 55401-1999 Telephone: 612-334-4100

July 15, 2002

## WARNING LETTER

## CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 02 - 35

Steven Boyum President Bombay Elevator, Inc. 6882 Highway 60 Boulevard Kenyon, Minnesota 55946

Dear Mr. Boyum:

An investigation of your medicated feed mill located at Kenyon, Minnesota, conducted by our investigator on February 5, 2002, found significant violations of the Federal Food, Drug, and Cosmetic Act (the Act). Our investigation determined that you caused the adulteration of the animal drugs monensin and chlortetracycline within the meaning of Section 501(a)(5) of the Act when you ordered, purchased, and sold these drugs for use in a manner that does not conform to an approved New Animal Drug Application (NADA) in accordance with Section 512. You also caused the adulteration of animal feed (a protein concentrate for sheep containing monensin and chlortetracycline labeled as "Custom Mix for Lambs") within the meaning of Section 501(a)(6) because its formulation and labeling fail to conform to an approved NADA in accordance with Section 512.

Lastly, your feed mill caused the misbranding of the medicated feed within the meaning of Section 502(a) and 502(e). The labeling that you supplied for the product was false and misleading in that was the manufacturer, not Bombay Elevator. The labeling was also incomplete.

The above is not intended as an all-inclusive list of violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

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You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your reply should be addressed to Compliance Officer Timothy G. Philips at the address on the letterhead.

Sincerely,

Director

Minneapolis District

Car TGP/ccl

xc: Richard M. Nystuen

Manager

Bombay Elevator, Inc. 6882 Highway 60 Blvd. Kenyon, MN 55946

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